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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,329	02/08/2001	Philip C. Gevas	ACG2AUSA	4824

7590 12/23/2003

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,329	GEVAS ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *15-18,25-27,29 and 44-49* is/are pending in the application.

4a) Of the above claim(s) *19-23 and 44-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-18,25-27,29,47-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Amendment filed 09/04/2003 is acknowledge. Claims 7, 19-24, 28,30-43 are canceled. Claims 44-49 are added. Claims 44-46 are withdrawn from consideration, as being drawn to a non-elected group (similarly to earlier withdrawn claims 19-23).

It is noted that, although applicant states that claim 29 was amended, no changes in the claim have been made. Further, since applicant did not provide direction to pages in specification providing support for limitations of claims 47-49 (which are not drawn to antibodies as asserted in applicant's remarks), these limitations are not considered in the rejections below.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 15-18,25-27,29,47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

A. Claim 15: it is not clear what "physiological changes due to gastrinemia" are meant. The pages indicated by applicant as providing support for the amendment do not have clear description of such physiological changes.

B. Claim 49 lacks antecedent basis as the base claim 15 does not address "physiopathological changes".

C. Claims 47,48: Not clear, what "substances" are meant.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 15-18,25-27,29,47-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment, does not reasonably provide enablement for prevention.

The burden of enabling the prevention of a disease (ie. the need for additional testing) would be greater than that of enabling a treatment due to the need to screen those humans susceptible to such diseases and the difficulty of proof that the administration of the drug was the agent that acted to prevent the condition. Further,

the specification does not provide guidance as to how one skilled in the art would go about screening those patients susceptible to hypergastrinemia, which may or may not accompany other gastric disorders (such as e.g., gastric cancer as noted by applicant in specification, p. 3, line 2-5). Nor is guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed compositions in preventing this disease state. Additionally, the specification fails to enable "treatment" to the extent such treatment includes the prevention of a disease state. Accordingly, undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention.

Claim Rejections - 35 USC § 103.

Applicant's arguments in regard to art rejections have been fully considered but were not deemed persuasive for the following reasons.

4. Claims 15-18,25-27,29,47-49 are rejected under 35 U.S.C.103(a) as obvious over by Watson et al (Cancer Research, 1996, or Int. J. Cancer, 1995; references AS and AR, respectively) or Gevas et al (US Patent 5,607,676) and further in view of Sundler, F. Acta Oncologica, 1991 30 (4) 419-27.

The instant claims, to the extent they read on the elected species, read on method for treating hypergastrinemia by administering an immunogenic composition comprised of a G17 fragment SEQ ID No. 1 (which is nine N-terminal residues of gastrin) linked to an immunogenic carrier in combination with another component selected from the group of proton pump inhibitor or histamine receptor blocker.

Watson et al.,1995 and 1996 references, teach immunogen, Gastrimmune, which is composed of nine N-terminal residues of gastrin linked to immunogenic carrier, such as diphtheria toxoid. This composition was used in rising anti-G17 antibodies; the later reduced gastrin level *in vivo.*

Gevas et al (US Patent 5,607,676[1]) teaches teach composed of G17 fragments, such as nine N-terminal residues of gastrin (e.g., col. 5, line 50), linked to immunogenic carrier, such as diphtheria toxoid. Said immunogen generates anti-gastrin antibodies which reduce level of gastrin and inhibit hypergastrinemia related disorders.

The references do not teach use of an additional component, such as proton pump inhibitor or histamine receptor blocker.

Modification to combine pharmaceutical agents, all known to be useful is anti-gastrin therapy, would have been obvious to one of ordinary skill in the art in view of

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[1]as well as other US patents of these applicants (Gevas et al. are the inventors of the instant invention as well) listed in Information Disclosure Statement filed 03/20/2001.

the fact that the courts have held that "it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be useful for the very same purpose". See In re Sisi, 169 USPQ 423, 426 (CCPA 1971). Because combination therapies are well-known in the art and because it would have been desirable to use plural therapies in order to maximize the effectiveness of, in this instance, anti-gastrin therapy, it would be *prima facie* obvious to one of ordinary skills in the art at the time the invention was made to be motivated to use the anti-gastrin immunogen of the instant invention not only as a sole active pharmaceutical agent, but also in combination with other known inhibitors of acid production, such as, for example, omeprazole or ranitidine. See, for example, Gevas, col. 1, lines 43-45 or abstract of Sundler et al. Selection of such acid production inhibitors would be obvious for an artisan.

Response to arguments

Applicant's arguments in regard to all of the references cited in the rejections, both under 35 USC § 102 and 103, are focused on the discussion of lack of recognition that hypergastrinemia is itself a disease worthy of treatment, and the treatment described in the references is not described to treat hypergastrinemia alone. The

claims, however, are not limited to treatment of one narrowly specified condition, but rather to treatment consequences of hypergastrinemia.

Conclusion.

5. No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 12, 2003

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb